

Blood-Stream Infection (CDC)

From: Lewis, Steve [Steve.Lewis@CareFusion.com]
Sent: Wednesday, December 02, 2009 6:52 PM
To: Blood-Stream Infection (CDC)
Cc: Crosby, Cindi
Subject: Comment Regarding Guidelines for Prevention of Intravascular Catheter-Related Infection - 2009 Draft

Federal Register Vol 74 No.211
 Guidelines for Prevention of Intravascular Catheter-Related Infection -2009 Draft
<http://wwwn.cdc.gov/publiccomments/>
<http://edocket.access.gpo.gov/2009/pdf/E9-26393.pdf>

Thank you for the opportunity to provide feedback on the draft guidelines. In full disclosure we represent CareFusion, Inc, which is the parent company for ChlorPrep® which offers a full suite of 2% Chlorhexidine and 70% isopropyl alcohol skin disinfectant products.

Line 1434

Prepare clean skin with 70% alcohol before peripheral venous catheter insertion [139]. Category IA

139. Maki DG, Band JD. A comparative study of polyantibiotic and iodophor ointments in prevention of vascular catheter-related infection. Am J Med 1981;70:739-44

The new guidance document strongly recommends that the patient's skin be prepped with 70% alcohol prior to peripheral venous cannulation. This recommendation is listed as a Category IA – which is defined as “strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies”. The recommendation is supported by one epidemiological study, Maki *et al.*, 1981, which evaluated the efficacy of three antimicrobial regimens; an iodophor ointment, an ointment containing polymyxin, neomycin and bacitracin; and use of no topical agent (control). Since the publication of this study there are several well-designed studies that have evaluated the impact of antiseptic agents in the preparation of the skin prior to cannulation.

Infection can be a costly and potentially devastating complication of IV therapy. While the frequency of peripheral intravenous catheter-associated infections is lower than central venous intravascular devices (IVD), the numbers of patients affected can be significant given the extensive use of peripheral intravenous catheters, not only in the United States, but throughout the world.¹ In 2006, Maki and colleagues prospectively evaluated peripheral intravenous catheters BSI rates and found that the infection rate was 0.5 per 1000 intravascular device days.² Coello and colleagues conducted a review in English hospitals between 1997 and 2001 and peripheral intravenous catheters were responsible for 3.9% and 8.4% of the hospital-associated infections dependent on type of hospital.³ Whatever type of IVD is used, a variety of factors during IVD insertion and individual patient characteristics can have a profound impact on the risk for IVD BSI.

Peripheral IV catheter infections are most often associated with *Staphylococcus epidermidis*, *Staphylococcus aureus*, and *Candida* infections.⁴ It is widely acknowledged that infectious complications can be significantly reduced by hand-hygiene, glove usage, site preparation with an appropriate antiseptic, and monitoring the site for signs infection.⁵

Peripheral IV site preparation with cutaneous antiseptics prior to intravascular catheter insertion can influence the risk for catheter colonization and infection. In a meta-analysis evaluating intravascular site preparation, chlorhexidine-containing antiseptics have been shown to be effective in diminishing rates of catheter colonization, and have shown varying efficacy in reducing intravenous device-related bacteremias. The authors stated “that use of chlorhexidine gluconate for patients requiring short-term vascular catheterization, both with central or peripheral catheters, will reduce the incidence of vascular catheter-related infections and decrease health care costs”.^{6,7} In addition, Garland, et al., demonstrated that, skin preparation and decontamination with 0.5% chlorhexidine gluconate in 70% isopropyl alcohol was more effective than 10% povidone-iodine in preventing colonization of peripheral catheters in neonates.⁸ In a randomized, controlled trial patients who had skin antisepsis before peripheral intravenous therapy with alcoholic 0.5% chlorhexidine gluconate had a lower risk of catheter related infection than those who had skin antisepsis with an alcohol swab followed by a povidoneiodine swab or a povidoneiodine swab followed by an alcohol swab.⁹ Subsequently, a comparison of 10% aqueous povidone iodine, 2% aqueous chlorhexidine gluconate, and 0.5% alcoholic chlorhexidine gluconate determined that both chlorhexidine solutions were similarly effective in preventing colonization of central venous and peripheral arterial catheters.¹⁰ Small and colleagues found that 2% chlorhexidine gluconate in 70% isopropyl alcohol was more effective in reducing the number of peripheral venous catheters that were colonized or contaminated than 70% isopropyl alcohol alone.¹¹

Based on recent clinical data we object to the recommendation: Prepare clean skin with 70% alcohol before peripheral venous catheter insertion and suggest to at least expand the recommendation to include 70% alcohol with 2% CHG based on current evidence in the literature.

References:

1. O'Grady, N.P., Alexander, M., Dellinger, E. P., Gerberding, J.L., Heard, S.O., Maki, D. G., et al. (2002) Guidelines for the prevention of intravascular catheter-related infections. Centers for Disease Control and Prevention: *Morbidity and Mortality Weekly Report-Recommendation Report*, 51, 1-29.
2. Maki, D. G., Kluger, D.M., & Crnich, C.J. (2006). The risk of bloodstream infection in adults with different intravascular devices: a systemic review of 200 published prospective studies. *Mayo Clinic Proceedings*, 81 (9), 1159-1171.
3. Coello, R., Charlett, A., Ward, V., Wilson, J., Pearson, A., Sedgwick, J., & Borriello, P. Device-related sources of bacteraemia in English hospital-opportunities for the prevention of hospital acquired bacteraemia. *J Hosp Infect*, 2003;53: 46-57
4. Tully JL, Friedland GH, Baldini LM, et al: Complications of intravenous therapy with steel needles and Teflon catheters. A comparative study. *Am J Med* 1981; 70:702.
5. Weinstein S. History of infusion therapy. In Weinstein S, Plumer A, ed. *Principles and Practice of Intravenous Therapy: An Illustrated Procedure*, 8th ed. Philadelphia. Lippincott, 2006:5.
6. Chaiyakunapruk N, Veenstra DL, Lipsky BA, et al: Chlorhexidine compared with povidone-iodine solution for vascular catheter-site care: a meta-analysis. *Ann Intern Med* 2002; 136:792-801.
7. Chaiyakunapruk N, Veenstra DL, et al. Vascular Catheter Site Care. The Clinical and Economic Benefits of Chlorhexidine Gluconate Compared with Povidone Iodine. *Clin Infect Dis*. 2003;37:764-71.
8. Garland JS, Buck RK, Maloney P, et al: Comparison of 10% povidone-iodine and 0.5% chlorhexidine gluconate for the prevention of peripheral intravenous catheter colonization in neonates: a prospective trial. *Pediatr Infect Dis J* 1995; 14:510-516.
9. LeBlanc A, Cobbett S. Traditional practice versus evidence-based practice for IV skin preparation. *Can J Infect Con*. 2000;Spring:9-14.
10. Valles J, Fernandez I, Alcaraz D, et al: Prospective randomized trial of 3 antiseptic solutions for prevention of catheter colonization in an intensive care unit for adult patients. *Infect Control Hosp Epidemiol* 2008; 29:847-853.
11. Small H, Adams D, Casey AL, et al: Efficacy of adding 2% (w/v) chlorhexidine gluconate to 70% (v/v) isopropyl alcohol for skin disinfection prior to peripheral venous cannulation. *Infect Control Hosp Epidemiol* 2008; 29:963-965.

Sincerely,

Stephen R. Lewis, M.D.
SVP, Chief Medical Officer
CareFusion
3750 Torrey View Court
San Diego CA 92130
858.617.2105

Cynthia T. Crosby
VP Global Medical Affairs
Infection Prevention
CareFusion
11400 Tomahawk Creek Parkway
Leawood, KS 66211

11400 Tomahawk Creek Parkway
Leawood KS 66211 USA

This message is for the designated recipient only and may contain privileged, proprietary or otherwise private information. If you have received it in error, please notify the sender immediately and delete the original. Any other use of the email by you is prohibited.

Dansk - Deutsch - Espanol - Francais - Italiano - Japanese - Nederlands - Norsk - Portuguese
Svenska: www.carefusion.com/legal/email

12/4/2009